

Title:	Placement of artificial bowel sphincters in the management of faecal incontinence – August 2003
Agency:	Medical Services Advisory Committee (MSAC) Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia http://www.msac.gov.au
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Aim
The safety, effectiveness and cost-effectiveness of the placement of artificial bowel sphincters in the management of faecal incontinence was assessed by systematic literature review.

Conclusions and results
There were no studies available that compared the safety or effectiveness of artificial bowel sphincter implantation to dynamic graciloplasty, for the treatment of faecal incontinence. Case series evidence indicates this procedure has uncertain benefits for the majority of patients and therefore patient selection is critical. Patients should be confined to those with severe faecal incontinence who have exhausted all conservative medical and surgical treatment avenues.

Safety:
Low-level evidence indicates a number of safety issues associated with the implantation of an artificial sphincter, that need to be addressed. Patients undergoing this procedure experience high explantation rates (33% of patients) in addition to a high level of harmful adverse events, which in many instances lead to surgical revision. Infection, ulceration, device malfunction and pain are common adverse events. A lack of follow-up data on unsuccessful procedures conducted on patients may indicate that these patients experienced detrimental physical or psychological effects. Uncertainty surrounds the life expectancy of the device due to a lack of long-term data.

Effectiveness:
All studies assessed in this review were case series. Appraisal of outcomes was not conducted on an intention-to-treat basis, leading to misleading findings in respect to the effectiveness of an artificial bowel sphincter. At the end of follow-up 68 per cent of patients had a functioning device and these patients experienced an average improvement in their continence of 62 per cent. No data were reported on the continence or quality of life of the remaining 32 per cent of patients with an explanted or non-functioning device. It is possible that these patients may have experienced a worsened degree of incontinence and quality of life.

Cost-effectiveness:
An analysis of the cost-effectiveness of this procedure was not possible due to a lack of high quality evidence on clinical effectiveness.

Recommendations
On the strength of the currently available evidence pertaining to the placement of artificial bowel sphincters in the management of faecal incontinence, public funding should not be supported for this procedure at this time.

Methods
Medline, Embase, Current Contents, Cochrane Library, SSCI, ProceedingsFirst, AustHealth, Cinahl, Australian Medical Index, APAIS, internet databases and sites, and reference lists were searched from 1966-2002. Study selection followed a protocol and varied according to the research question being addressed. The evidence was assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council. Study quality was appraised using standard checklists.

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